UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. et al., Plaintiffs, v. EMCURE PHARMACEUTICALS LIMITED et al., Defendants.	Civil Action No. 18-2065 (SRC) (Consolidated) **OPINION & ORDER**
SUMITOMO DAINIPPON PHARMA CO., LTD. et al., Plaintiffs, v. AUROBINDO PHARMA LTD. et al., Defendants.	Civil Action No. 18-2620 (SRC)

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Sunovion Pharmaceuticals Inc. and Sumitomo Dainippon Pharma Co., Ltd. and Defendants Emcure Pharmaceuticals Ltd., Aurobindo Pharma Ltd., Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Lupin Ltd., Sun Pharma Global FZE, Accord Healthcare Inc., Amneal Pharmaceuticals, LLC, InvaGen Pharmaceuticals, Inc., Torrent Pharmaceuticals Ltd., Watson Laboratories Inc., and Zydus Pharmaceuticals (USA) Inc. (collectively,

"Defendants"). In these consolidated patent infringement actions, the parties seek construction of claim terms in U.S. Patent No. 9,815,827 ("the '827 patent"), and a subset of the parties seek construction of claim terms in U.S. Patent No. 9,907,794 ("the '794 patent").[1]

These consolidated cases are patent infringement actions under the Hatch-Waxman Act. Plaintiffs are pharmaceutical manufacturers which own the '827 and '794 patents. The '827 patent is directed to methods of using lurasidone, the active ingredient in Plaintiffs' Latuda ® product. The'794 patent is directed to particular lurasidone formulations. Defendants are pharmaceutical manufacturers who seek to manufacture and distribute generic versions of Latuda®.

After opening and responsive briefs were filed, the Court allowed submission of a reply brief. The Court heard oral argument on September 26, 2018, and allowed the parties to submit post-hearing supplemental briefs.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v.

[1] Plaintiffs do not assert the '794 patent against Defendants Torrent, Amneal, or Lupin. Those Defendants, along with Dr. Reddy's and Sun Pharma, take no position on the construction of the '794 patent.

Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
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> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms

The parties dispute a set of related claim terms in the '827 patent and a single term in the '794 patent. At issue in the '827 patent is the meaning of a set of claim terms which, generally, describe the patented method as "without a clinically significant weight gain" or as "without a weight gain."

Plaintiffs, in their opening and responsive briefs, had proposed that the weight gain terms did not limit the claims; in the alternative, Plaintiffs proposed that the weight gain phrases should be understood to have the phrase "on average" inserted into them. Prior to oral argument, Plaintiffs abandoned their primary argument and conceded that the weight gain terms in the '827 patent are claim limitations. Then, in the post-hearing supplemental briefing, Plaintiffs abandoned their proposed alternative construction that sought to interpret the weight gain terms as applying to population averages. Instead, Plaintiffs now ask the Court to construe "a patient" in the '827 patent to mean "a patient population." Plaintiffs argue that, when the Court reaches the infringement analysis, the Court will need to figure out whether to use averages or frequency counts to assess weight gain on a population-wide basis, but that it need not deal with that issue during claim construction.

Although Plaintiffs no longer propose that "on average" be inserted into the claims, their new proposed construction rests on arguments and evidence that were raised in the context of the "on average" construction. Examination of the evidence and arguments concerning weight gain, averages and frequencies in the '827 patent remains relevant. The fact that Plaintiffs now propose a different construction does not erase their previous arguments. Consideration of the

arguments that supported "on average" reveals some conflicts between their prior proposed construction and their latest one.

A. Do the '827 weight gain terms refer to populations and averages?

Plaintiffs had contended that the weight gain terms[2] do not limit the claims, but have conceded that they do so. Plaintiffs had argued, in the alternative, that the weight gain terms, if found limiting, "refer to the average measure of baseline body weight gain." (Pls.' Br. 15.) As of the supplementary briefing, Plaintiffs propose that, instead, the Court should construe "a patient" to mean "a patient population."[3] Defendants contend that the terms have their ordinary meaning, and that "a patient" means "one or more patients."

For example, consider claim 1:

> 1. A method for treating schizophrenia in a patient without a clinically significant weight gain, comprising: administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl met- hyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Plaintiffs had proposed this construction of the body of the claim: "administering orally to the patient [the chemical] or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that, on average, the baseline body weight of patients undergoing treatment does not

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[2] "Weight gain language," or "weight gain terms," as used herein, refers to phrases like, "such that the patient does not experience a clinically significant weight gain."

[3] In the claims, the weight gain phrases sometimes refer to "a patient" and sometimes to "the patient." Neither the parties nor this Court have treated the difference in article used as meaningful in the context of this analysis.

increase by 7%."[4] Now, however, Plaintiffs' proposed construction for claim 1 would construe "the patient" to mean "the patient population."

Plaintiffs have proposed that the phrase "weight gain," in the context of the '827 patent, "would be well understood by those skilled in the art to refer to the average weight gain across a population of patients." (Pls.' Br. 16.) In support, Plaintiffs offered the declaration of their expert, Dr. Newcomer. Dr. Newcomer states:

> 29. In evaluating treatment methods using various drugs, the data that those skilled in the art most generally use is data representing the average or mean measured across a sample of observed patients. Other relevant data used in evaluating treatment methods include the frequency of occurrence of certain favorable or unfavorable events of interest. When prescribing a drug to a patient, a physician does not know in advance how the drug will perform in that specific patient, but understands what the expectations are based on the known averages or frequency of events in a previously treated population.
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> 30. With this background knowledge, and when reading the claims of the '827 patent together with the patent's specification, a person skilled in the art understands that the "weight gain" concepts recited in the claims are referring to the average effects experienced within the population of patients undergoing treatment.
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> 31. The '827 patent specification describes a clinical trial on lurasidone that supports my opinion that a person skilled in the art would read the weight gain terms in the claims as referring to the average medication-related body weight gain compared to baseline among the patients undergoing treatment. In the discussion of that clinical study, the data for both efficacy and safety of lurasidone is described in terms of the sample of patients evaluated, as is the general practice for reporting the results of clinical studies. The average efficacy data is presented in Tables 2 and 3. And the safety data, which reports adverse events that were "observed in 10% or more of patients" in the population, is presented in Table 5 and the surrounding text. The specification reports that "114 subjects among 149 subjects (77%) showed adverse events," referring to the rate of adverse

[4] This proposed construction will be considered in two stages. First, the Court will consider the subject of populations and averages. Then, the Court will consider the " 7%" term.

events seen in the study sample as a whole. ('827 patent at 7:42-44.)

32. As for weight gain specifically, the specification reports that weight gain "was not observed" in the study population tested. (Id. at 7:66-67.) There is no specific average or mean weight gain reported for the population undergoing treatment.

33. A person skilled in the art would understand that the invention claimed in the '827 patent is based, at least in part, on the clinical trial described in the specification. As such, a person skilled in the art, when reading the claims that are based in part on that clinical trial, would understand that terms such as "weight gain" refer to average or mean weight effects experienced within the population of patients undergoing treatment.

Dr. Newcomer thus concluded that the skilled artisan would understand the term "weight gain" to refer to average weight gain in a population.

As to the proposition that the phrase, "weight gain," itself, in the context of the patent, refers to average weight gain in a population, Dr. Newcomer's first paragraph undermines this position and his own conclusion. Dr. Newcomer states that the skilled artisan may use either an average or a frequency count in evaluating a treatment method; without using these words, it is apparent that Dr. Newcomer means that skilled artisans use both averages and frequency counts as summary statistics of research data. Dr. Newcomer states that the skilled artisan may use one, *or* the other. This is at odds with Plaintiffs' prior position. Plaintiffs had argued that the skilled artisan would consider just one, the average.[5]

The specification of the '827 patent contains no clear statements about how to assess weight gain. In fact, the specification says very little about weight gain at all. The phrase

[5] At oral argument, the Court queried Plaintiffs about this issue, and Plaintiffs stated that they could accept the use of either averages or frequencies. Plaintiffs' post-hearing brief puts that position in writing. That modified position, however, contradicts the conclusion of their expert and their previous argument.

"weight gain" appears only once in the specification of the '827 patent, in this statement about the frequency of side effects in a clinical study: "Either body weight gain, bulimia, impotence, erectile dysfunction or convulsion was not observed." '827 patent, col.7 ll.66-67. Table 5, which lists adverse events observed in the study, contains data in the form of frequencies and percentages. There are no averages in Table 5, nor are averages mentioned in the specification's discussion of Table 5. Plaintiffs, nonetheless, argue that the applicants here are discussing the population tested rather than individual data. This may be true, but, again, the fact that the patentees summarized the side effects experiences obtained in a clinical study does not mean that they conceived of the invention as a method to treat populations, not individuals.

The specification thus mentions weight gain only in the context of describing the results of a clinical study of side effects of lurasidone treatment. Plaintiffs contend that the way in which the patentees presented clinical study results supports their proposed "population" construction. Table 5 contains only frequency counts, as raw frequencies or percentages; it contains no averages. Moreover, nearly the entire discussion of the side effects data in the specification refers only to frequencies, not to averages.[6] '827 patent, col.7 l.42-col.10 l.5. The intrinsic evidence does not support the Plaintiffs' contention that the skilled artisan, reading the patent, would choose the average weight gain in the population, rather than the frequency of weight gain in the population, to summarize side effects data and performance.

Having abandoned their "on average" construction, the evidence in the specification that Plaintiffs point to in support of their "population" construction concerns: 1) clinical study results;

[6] Only Table 8 contains averages, concerning three side-effects rating scales. '827 patent, col.10 ll.5-19. The claim terms at issue do not concern rating scales.

and 2) plurals. As to clinical study results, Plaintiffs point out that, in the specification, the results are summarized for groups of patients. What is the logical connection between this point and the proposed construction? Yes, as a general rule, people often find summary statements about groups of people to be useful. Plaintiffs have not persuaded this Court that the fact that the patentees used summary statistics to summarize the results of clinical studies – the kind of summary study statistics that this Court sees routinely in treatment method patents – says anything about the meaning of particular claim terms.

Plaintiffs also point to the use of plural forms, "patients," in the specification. It is true that, in some places, the specification uses the plural form, "patients," while in others, it uses the singular form, "patient." Plaintiffs have not shown that the use of the plural form in some places reveals that the inventors understood the invention as a method for treating populations rather than individuals.

Next, Plaintiffs cite the file history but, again, they point to an example of the applicants using summary statistics to describe clinical study results.[7] Again, this does not illuminate the meaning of any claim term. This Court finds no intrinsic evidence that supports any of Plaintiffs' proposed constructions.

Lastly, in Plaintiffs' opening and post-hearing briefs, Plaintiffs point to parts of the Latuda® label and labels of other pharmaceuticals. The Court does not find this extrinsic evidence helpful to understanding any terms in the claims in the '827 patent. Thus, this Court

[7] For example, in the applicants' remarks in response to the Office Action of October 19, 2016, the applicants discussed a research study and cited weight gain summary statistics from it. ('827 File History Ex. at LATUDA00000211.) The discussion contains some summary statistics that are averages, and some that are percentage incidence rates. (Id.)

finds no intrinsic or extrinsic evidence which supports the "population" construction.

To support the "population" construction, Plaintiffs rely principally on the Federal Circuit's decision in Braintree Labs., Inc. v. Novel Labs., Inc., 749 F.3d 1349, 1357 (Fed. Cir. 2014), in which the Court dealt with a composition patent and construed "a patient" to mean "a patient population." It is well understood that Federal Circuit decisions cannot be read as codebooks, and that the construction in a patent in one case cannot be used as a translation for language in an unrelated patent. This Court concludes that Braintree is distinguishable.

At the outset, this Court notes that, in Braintree, the Federal Circuit construed "a patient" to mean "a patient population." In the instant case, Plaintiffs did not initially ask this Court to construe "a patient" to mean "a patient population." It was only after oral argument that they proposed this construction.

Nor does the legal reasoning the Braintree Court applied fit what Plaintiffs have proposed in the instance case.[8] The Federal Circuit's reasoning had its foundation in another preamble construction case, Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997) (citations omitted), in which the Federal Circuit held:

> The determination of whether preamble recitations are structural limitations or mere statements of purpose or use can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim. The inquiry involves examination of the entire patent record to determine what invention the patentee intended to define and protect.

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[8] In their post-hearing brief, Defendants distinguish Braintree on another basis: it concerned a composition patent, rather than a method patent, as in the instant case. One consequence of this difference, Defendants argue, is that a generic pharmaceutical manufacturer can only infringe indirectly, whereas the Braintree majority expressed concern about the impact of the construction on finding direct infringement. The Court finds this to be a meaningful distinction.

The Braintree Court applied this principle and concluded that the patentees intended to protect an invention that was better understood in terms of "a patient population," rather than "a patient." Braintree, 749 F.3d at 1357. The Federal Circuit found support for this construction in the specification in several places. Id.

The '827 patent, on the other hand, does not suggest the same. Rather, again consider claim 1:

> 1. A method for treating schizophrenia in a patient without a clinically significant weight gain, comprising: administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl met- hyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Note the terminal phrase, "such that the patient does not experience a clinically significant weight gain." This can only be understood in terms of an individual.[9] A group of patients cannot meaningfully be said to experience a clinically significant weight gain, on a group-wide or average basis. Individuals experience weight gain; while summary statistics may summarize the weight gain of all of the members of the group, the group does not "experience" collective weight gain. Plaintiffs have not persuaded this Court that the '827 patentees understood "the patient" to mean "the patient population."

Lastly, as Defendants had argued, the effect of inserting "on average" into the claim language would be "to cover the treatment of individual patients who do gain weight – exactly what the plain language prohibits." (Defs.' Br. 3.) Although Plaintiffs have now abandoned the

[9] If we rewrite claim 1 of the '827 patent to follow Braintree, claim 1 states "such that the patient population does not experience a clinically significant weight gain," which makes no sense.

"on average" construction, the "population" construction has the same effect – except that now, the effect is latent for the time being, to be uncovered and addressed later. Plaintiffs have clearly stated that their plan is to persuade the Court to determine infringement by looking at weight gain across a population, whether through the use of averages or of frequencies. But, as to Defendants' argument that this construction recaptures surrendered subject matter, this is the same thing.[10] If, as Plaintiffs contend, the patent covers the treatment of populations which do not have clinically significant weight gain, rather than individuals, this opens the door to finding that patients who do gain weight are infringers. Plaintiffs' "population" construction could thus have the effect of negating the express limits on scope stated in the claims – which limit the scope of the invention to patients who *do not* gain weight – and extending the scope of patent protection to include exactly that group of patients that the applicants expressly excluded – the patients who *do* gain weight.

In Braintree, the Federal Circuit explained the reasoning for the decision that "a patient" means "a patient population." In particular, the Court wrote: "This definition of a patient is consistent with the 'invention the patentee intended to define and protect.'" Braintree, 749 F.3d at 1357. This is one of the fundamental principles of claim construction, as the Federal Circuit has explained at greater length elsewhere:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention

[10] Deferring until trial the inquiry into the method for assessing weight gain, as Plaintiffs now propose, conceals the improper broadening of claim scope that is latent in the "population" construction. While the "on average" construction made the attempted recapture of surrendered subject matter conspicuous at claim construction, the "population" construction leaves it latent.

> will be, in the end, the correct construction. A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.

Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (citations omitted). Thus, in Braintree, the Federal Circuit concluded that the construction, "a patient population," best aligned with the patent's description of what the inventor actually invented. The construction, "a patient population," therefore neither broadened nor narrowed the scope of the claim or of the invention.

In contrast, here, Plaintiffs have proposed a construction – "a patient population" – that greatly broadens the scope of the claim, and broadens it well beyond what the inventors actually invented. Although Plaintiffs have now argued that the Court need not, at this juncture, contemplate how infringement is determined, it seems probable that the procedure would involve assessing the weight gain of individuals who receive lurasidone treatment, but then combining the results for patients who gained weight and patients who did not, and then computing either the average weight gain or looking at summary frequency statistics for the population. If we assess infringement across a population in such way, the claims could also cover patients who do gain weight – as long as their population (however that is defined) does not gain weight (however that is determined). As Defendants argue, this has the perverse effect of letting the claims cover people who, by the clear language of the claims, are outside the metes and bounds of the invention.

To put this another way, Plaintiffs' proposed construction could operate to make infringers out of physicians who treated patients with generic lurasidone or the patients themselves, if those patients gained weight – if the patients are included in a population which,

on some summary measure, does not show clinically significant weight gain overall. This result is directly contrary to the plain meaning of the claim language: only physicians who treat patients with generic lurasidone (or the patients themselves), when those patients do not gain weight, should be infringers. This application of Plaintiffs' proposed construction leads to the absurd result of infringement even if the patient's use of lurasidone causes a significant weight gain. Because Plaintiffs have not explained how infringement would be determined, the Court is left to wonder whether a physician who treated only patients who gained weight could become an infringer by virtue of having those patients eventually included in some larger population which, on average or by some summary measure of frequency, shows no clinically significant weight gain. In such a scenario, the infringement determination has nothing to do with the physician's conduct, or with the patients' conduct, but is based on arbitrary groupings of results after treatments are concluded. When the infringement determination is this arbitrary, the patent fails to serve its function of notifying the public of the boundaries of the invention in a way that allows definiteness and certainty about what is claimed.

Moreover, Plaintiffs' proposed construction broadens the scope of the claims to cover subject matter that the applicants surrendered. Consider the Supreme Court's holding in Smith v. Magic City Kennel Club, Inc., 282 U.S. 784, 789-90 (1931) (citations omitted):

> The case, in our opinion, thus calls for the application of the principle that where an applicant for a patent to cover a new combination is compelled by the rejection of his application by the Patent Office to narrow his claim by the introduction of a new element, he cannot after the issue of the patent broaden his claim by dropping the element which he was compelled to include in order to secure his patent. . . . The applicant having limited his claim by amendment and accepted a patent, brings himself within the rules that if the claim to a combination be restricted to specified elements, all must be regarded as material, and that limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and

> looked upon as disclaimers. The patentee is thereafter estopped to claim the benefit of his rejected claim or such a construction of his amended claim as would be equivalent thereto.

Applying Smith requires considering the prosecution history of the '827 patent.

The prosecution history shows that the application which led to the '827 patent was filed on August 28, 2014 as a continuation of pending prior application number 10/525,021. ('827 File History Ex. at LATUDA00000050-52.) The proposed claims submitted in this continuation application do not mention weight or weight gain. (Id. at LATUDA00000071-73.) Instead, proposed claims 1 and 8 disclose that the treatment method is "without being accompanied by any extrapyramidal symptoms."[11] (Id. at LATUDA00000071-72.) The proposed abstract does not mention weight or weight gain but, instead, states that the treatment works "without being accompanied by extrapyramidal symptoms." (Id. at LATUDA00000074.)

The applicants filed a preliminary amendment with the continuation application, which cancelled all pending claims and submitted new claims 20 through 27. (Id. at LATUDA00000076-79.) Claim 20, the only independent claim, began as follows: "A method for treating schizophrenia in a patient, without causing clinically significant body weight gain in the patient, the method comprising administering to the patient a dose of 5 mg to 120 mg of the active compound . . ."[12] (Id. at LATUDA00000078.) The proposed claims in the preliminary amendment contain no other language related to weight or weight gain. On October 19, 2016,

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[11] The proposed specification explains: "However, phenothiazine derivatives, phenothiazine analogues, and butyrophenone derivatives may cause serious side effects of extrapyramidal symptoms showing parkinsonism such as the stiff gait of skeletal muscles, tremor of muscles, lack of facial expression, salivation, etc." (Id. at LATUDA00000054.)

[12] On October 5, 2015, the applicants filed an additional preliminary amendment which made a minor change to claim 20. (Id. at LATUDA00000134.)

the PTO issued an office action rejecting all claims as obvious over the Wong reference. (Id. at LATUDA00000162.)

In response, the applicants filed both new claims and amendments to the existing claims which included additional language related to weight gain. (Id. at LATUDA00000193-204.) Specifically, the applicants added weight gain language to numerous claims: for example, to the body of claim 20, to the preamble and body of claim 28, and new independent claims 45, 60, and 76, all of which contain the weight gain language in both the preamble and the body fo the claim. (Id.) In the remarks following the amendments, the applicants stated:

> The present application relates to a method of treating a patient with schizophrenia or manic depressive psychosis (bipolar disorder) without inducing a clinically significant weight gain. A problem with many antipsychotics used to treat these conditions is an undesirable weight gain. The present invention is based on the discovery that a clinically significant weight gain can be avoided by the use of the active compound [chemical name] . . .
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> Wong fails to teach treating schizophrenia in a patient without a clinically significant weight gain by administering the active compound of Claim 20 "at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain." Applicant respectfully submits that Wong rather discourages one from using the active compound of Claim 20 because the reference recognizes that anti psychotic drugs such as the claimed active compound cause side effects, in particular, a significant weight gain.

(Id. at LATUDA00000205-06.) In these remarks, the applicants sought to overcome an obviousness rejection based on the Wong reference; they distinguished Wong as not having disclosed a treatment for schizophrenia that did not produce clinically significant weight gain.

On July 17, 2017, the PTO issued a notice of allowability of all claims. (Id. at LATUDA00000242.) In the accompanying remarks, the examiner stated the "reasons for allowance" as follows, in its entirety:

> The closest prior art of record does not teach, disclose or suggest the claimed

> invention. The original specification describes relevant clinical studies. For example, the specification states on page 8, lines 1-3, that "[t]he efficacy and safeness were studied where SM-13496 at a dose of 40 mg or 120 mg, or a placebo was orally administered once a day 6 weeks after placebo washout." Table 5 on page 11 shows "[a]dverse events observed in 10% or more of the patients," and it is reported on page 12 that "either body weight gain, bulimia, impotence, erectile dysfunction or convulsion was not observed." Therefore, the ratio of patients who experienced a weight gain after 6 weeks of administration was less than 10%. These results are significant and unexpected because conventional antipsychotic drug caused serious side effects such as undesired metabolic changes (e.g., hyperglycemia and dyslipidemia) and cardiovascular adverse reaction, which were considered as closely linked with a weight gain. The claimed invention is therefore distinguished from prior art of record and is novel.

(Id. at LATUDA00000243.) It is completely clear from the prosecution history that the applicants added the weight gain terms during prosecution to overcome an obviousness rejection. The applicants narrowed the scope of their claims in order to obtain a patent. The amendments unmistakably surrendered coverage of treatments with lurasidone that produce weight gain. Plaintiffs now propose a construction that, to some extent, recaptures surrendered subject matter – treatment of patients who experience clinically significant weight gain. Such a construction is barred under Smith.[13]

Plaintiffs argue that Braintree supports construing "a patient" to mean "a patient population." If, however, this Court were to follow Braintree and construe "a patient" in the '827 patent as "a patient population," this would cause problems in other claims in that patent. Consider, for example, claim 6:

> The method of claim 1, wherein said patient has a BPRS score of at least 42 and wherein the patient's BPRS score is significantly reduced from a baseline

[13] See also Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.")

measurement prior to the administering.

If "patient" is construed to mean "patient population," claim 6 makes no sense. A BPRS score of 42 is clearly a characteristic of an individual, as a population cannot meaningfully be said to have a BPRS score.[14] "The fact that we must look to other claims using the same term when interpreting a term in an asserted claim mandates that the term be interpreted consistently in all claims." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995). The term "patient" in claim 1 thus cannot be construed as "patient population" without either depriving claim 6 of meaning or violating this principle.[15]

This Court concludes that today's decision is consistent with the reasoning the Federal Circuit relied on in Braintree. In Braintree, the Court concluded that construing "a patient" to mean "a patient population" was "consistent with the 'invention the patentee intended to define and protect.'" Braintree, 749 F.3d at 1357. In the instant case, construing "a patient" to mean "a patient population," as Plaintiffs propose, is inconsistent with the invention the patentees intended to define and protect.

The Federal Circuit has held:

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[14] The specification states that "BPRS" refers to the Brief Psychiatric Rating Scale, an index of "the effects of schizophrenia." '827 patent, col.3 ll.20-21. The specification reports on a clinical trial in which one criterion for subject selection was "Patients having 42 or more of Extracted-BPRS Score as well as 4 or more of CGI-S Score." Id. at col.5 ll.26-27. The BPRS is clearly an evaluation technique used to assess the effects of schizophrenia in an individual patient.

[15] Moreover, consider the use of "patient" in the specification, which states that schizophrenia is a psychosis which develops during adolescence, "and after a chronic course, the personality of patient [sic] is progressively decayed." '827 patent, col.1 ll.20-21. Again, if "patient" is construed as "patient population," this makes no sense. Only an individual has a personality; a population does not.

> The general rule is that the court must presume that the terms in the claims mean what they say and construe them according to their ordinary and accustomed meaning. This 'heavy presumption' in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence.

Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1177 (Fed. Cir. 2002) (citations omitted). Plaintiffs have not overcome the heavy presumption that "a patient" has its ordinary meaning.[16] This Court concludes that the "a patient" does not mean "a patient population."[17] Rather, "a patient" and "the patient" mean "one or more patients." See 01 Communique Lab., Inc. v. LogMeIn, Inc., 687 F.3d 1292, 1297 (Fed. Cir. 2012).

B. In the '827 patent, what weight gain is "clinically significant?"

The parties disagree about how and where to draw the limiting line for clinically

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[16] For the reasons stated, this Court rejects Plaintiffs' proposed construction that "a patient" means "a patient population." The Court further notes that, had it agreed with Plaintiffs, it would have soon been confronted with the difficult challenge of figuring out the implications of this construction for the infringement analysis. In short, the "population" construction raises the question: how does one determine clinically significant weight gain in a population? Whose weight gets included? How many people get included in the group and how are they selected? Plaintiffs thus have proposed a construction that raises a host of questions about implementation that have not been addressed.

[17] In reply, Plaintiffs argue that Defendants' expert opined that physicians frequently make decisions based on the average known performance of medications. This is likely true, but does not provide a justification for grafting new limitations onto issued claims. As the Federal Circuit colorfully stated:

> A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a "nose of wax." In other words, evidence extrinsic to the patent and prosecution history, such as expert testimony, cannot be relied on to change the meaning of the claims when that meaning is made clear by those documents.

Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995) (citations omitted).

significant weight gain, but also on whether this issue should be decided at claim construction. Defendants contend that no construction is needed, and they intend to show at trial that the term is indefinite. Plaintiffs point to a number of pieces of extrinsic evidence to support their position that "clinically significant weight gain" here means weight gain 7%.

The Court agrees that it makes sense to wait until summary judgment or trial to decide these issues, because both require hearing extrinsic evidence in order to make factual determinations about how the skilled artisan would understand "clinically significant weight gain."

C. The '794 patent: "a pregelatinized starch"

The parties dispute the meaning of the claim term, "a pregelatinized starch," which appears in independent claims 1 and 15 in the '794 patent. Plaintiffs propose that this has its ordinary meaning and the element must be present in the composition, but in any amount. Defendants propose that this Court should construe the term as limited to a range of 10% to 50% by weight of the preparation. Defendants make two arguments: 1) the '794 patent specification discloses this range; and 2) the applicants disclaimed the subject matter outside this range during prosecution of the parent '085 patent.

Defendants' first point may be dealt with briefly. Defendants point to a number of places in the specification where the patentees' examples contain pregelatinized starch in the range of 10% to 50%.[18] The problem is that Defendants seek to import a characteristic of the embodiments into the claims as a limitation. The Federal Circuit has — in its own words -

[18] As shorthand, this Opinion generally refers to the starch percentage without noting that this is a percentage based on weight.

"repeatedly warned" against limiting claims to particular embodiments: "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." Phillips, 415 F.3d at 1323. The Federal Circuit has explained:

> The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language. Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.

Superguide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004); see also Sumitomo Dainippon Pharma Co. v. Emcure Pharm. Ltd., 887 F.3d 1153, 1158 (Fed. Cir. 2018) ("Appellants' claim construction arguments conflict with *Pfizer* and other precedent because they seek to import limitations from the specification into the claim.") Moreover, the requirements for importing such a limitation are exacting: "Generally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a clear intention to limit the claim's scope with words or expressions of manifest exclusion or restriction." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (quotation omitted). Defendants have not pointed to any expressions of manifest exclusion or restriction in the specification which could justify restricting the claims to any particular embodiment. In fact, Defendants' briefs completely overlook the Federal Circuit requirement of "words or expressions of manifest exclusion or restriction."

Next, Defendants argue that, during prosecution of the parent '085 patent, the applicants disclaimed amounts of pregelatinized starch outside the range of 10% to 50%, and that this disclaimer binds the interpretation of the same claim term in the '794 patent. Plaintiffs contend

that the prosecution history of the parent application shows no disclaimer. While the parties dispute the existence of any disclaimer, they agree that the subsequent prosecution history shows no rescission of any disclaimer.

The relevant undisputed facts are as follows. On October 31, 2007, the applicants filed application 11/919,678, which contained independent claims with the element of "a pregelatinized starch" without limitation as to the amount. (Reig-Plessis Dec. Ex. K at DEF-LURAS0008238.) U.S. Patent No. 8,729,085 (the "'085 patent") issued from this application on May 20, 2014. As ultimately issued, independent claim 1, on which the majority of the claims depend, contains this limitation: " the pregelatinized starch is incorporated in an amount of 20 to 50% (wt/wt) based on the weight of the preparation." Independent claim 20 contains this limitation: "the pregelatinized starch is incorporated in an amount of 20 to 50% (wt/wt) based on the weight of the oral preparation . . ." Independent claims 26 and 27 contain this limitation: "the pregelatinized starch is incorporated in an amount of 20 to 30% (wt/wt) based on the weight of the preparation . . ." Thus, every claim in the '085 patent limits the pregelatinized starch in the formulation to the range of 20% to 50%, or to a narrower range within that range.

During prosecution of the '085 patent, the following events occurred. Original claim 1 required "a pregelatinized starch" without any restriction as to amount; original claim 8, depending on claim 1, restricted the amount to the range of 10% to 50%. (Reig-Plessis Dec. Ex. K at DEF-LURAS0008238-39.) In an office action, the examiner rejected the pending claims as obvious over the Fujihara reference in view of the Salpekar reference. (Reig-Plessis Dec. Ex. L at DEF-LURAS0008541.) The examiner explained that, while Fujihara did not disclose the use of pregelatinized starch ("PGS"), Salpekar disclosed the use of PGS in the amount of 5% to 15%.

(Id. at DEF-LURAS0008543.) In response, the applicants filed an amendment, dated May 24, 2010, which amended all relevant claims to require that the pregelatinized starch be in the range of 10% to 50%. (Reig-Plessis Dec. Ex. M at DEF-LURAS0008581-82.) The examiner maintained the obviousness rejection over Fujihara and Salpekar in several subsequent office actions. (Reig-Plessis Dec. Ex. N at DEF-LURAS0008607; Reig-Plessis Dec. Ex. O at DEF-LURAS0008663; Reig-Plessis Dec. Ex. P at DEF-LURAS0008748.) In the last of this group, the examiner explained that the PGS range of 5% to 15% disclosed in Salpekar overlapped with the range in the claims of 10% to 50%. (Reig-Plessis Dec. Ex. P at DEF-LURAS0008748.) Despite this, the applicants submitted amended independent claims that continued to limit PGS to the range of 10% to 50%. (Reig-Plessis Dec. Ex. R at DEF-LURAS0008688.) The evidence of record does not show how the PTO responded to that amendment. On January 24, 2014, the applicants submitted a supplemental amendment which changed the PGS range of 10% to 50%, to 20% to 50%. (Reig-Plessis Dec. Ex. S at DEF-LURAS0008895.) In the remarks that accompanied the amendment, the applicants wrote:

> The Examiner telephoned Applicant's representative on January 22, 2014, proposing that Applicant change the lower limit of the pregelatinized starch in claims 1 and 37 from 10% (wt/wt) to 20% (wt/wt), delete the recitation regarding the amount of water-soluble excipient from claim 31, and cancel claims 27 and 45 in order to place the above-identified application in condition for allowance. To comply with the Examiner's proposals and solely for the purpose of placing this application in condition for allowance, claims 1, 31, and 37 are amended, and claims 27 and 45 are canceled herein. Applicant is not disclaiming any subject matter by the amendments provided herein, and reserves the right to file a continuation application with claims that include the canceled subject matter.

(Id. at DEF-LURAS0008901.) On February 3, 2014, the PTO issued a notice of allowance. (Reig-Plessis Dec. Ex. T at DEF-LURAS0008905.) On May 20, 2014, the '085 patent issued, with independent claims limiting PGS to the range of 20% to 50%.

On February 18, 2014, the applicants filed a continuation application of the previous application, recorded as application 14/183,283, which matured into U.S. Patent No. 8,883,794, containing claims limited to compositions with PGS in the range of 20% to 30%. (See generally Defs.' Br. at 21 n.4.) On October 10, 2014, the applicants filed a continuation application of the previous application, recorded as application 14/512,189, which matured into U.S. Patent No. 9,555,027, containing claims limited to compositions with PGS in the range of 10% to 50%. (Id.) On June 8, 2015, the applicants filed a continuation application of the previous application, recorded as application 14/733,204, which matured into the '794 patent. (Id.) The '794 patent thus descended from the original application (11/919,678), which matured into the '085 patent, via a chain of continuation applications.

As just stated, in the amendment filed on May 24, 2010, the applicants amended proposed independent claims 1, 2, and 3 by adding a limitation, "and the pregelatinized starch is incorporated in an amount of 10 to 50% (wt/wt) based on the weight of the preparation." (Reig-Plessis Dec. Ex. M at DEF-LURAS0008581-82.) In the accompanying remarks, the applicants explained that they sought to traverse the obviousness rejection over Fujihara in view of Salpekar. (Id. at DEF-LURAS0008586.) The applicants discussed Fujihara, arguing that it did not teach or suggest the invention. (Id. at DEF-LURAS0008587-88.) The applicants then wrote:

> Fujihara's shortcomings are not overcome, even if, for the sake of argument it were combined with Salpekar *et al.*
>
> Although Salpekar *et al.* teaches a composition comprised of a pharmaceutically active ingredient and pregelatinized starch, and even if arguendo some of such compositions may allow short dissolution time and shorter [sic] the dissolution and disintegration time, as the Examiner postulates, Salpekar *et al.* nonetheless does not provide any motivation towards the claimed inventions.
>
> . . .

> Even if, for the sake of argument, Salpekar *et al.* were combined with Fujihara, a person skilled in the art cannot arrive at the inventive content rates of pre gelatinized starch (10 to 50% (wt/wt)) as below. Although Salpekar *et al.* teaches that effective amount of PGS (i.e., pregelatinized starch) is from about 5 or less to about 15 or more parts per 100 parts of the composition . . ., Salpekar's compositions which substantially show significant technical effects are only those supported by Examples (i.e., 4.45-8.85% of PGS), in view of Salpekar's disclosure that the PGS is included in an amount effective for imparting to the composition the capability of being formed into tablets having high hardness, short disintegration time . . . and short dissolution time . . .
>
> . . .
>
> Therefore, those skilled in the art may understand that 4.45-8.85% of PGS is preferable for a tablet having a short disintegration time and a short dissolution time. Accordingly, a person of ordinary skill in the art cannot arrive at pregelatinized starch (10 to 50% (wt/wt)), beyond Salpekar's preferable ranges, which can cause compositions comprising high content rates of the active ingredient with the advantageous dissolution profiles.

(Id. at DEF-LURAS0008588-90.)

Defendants argue: "By amending the claims to require a specific amount of pregelatinized starch, the patentee clearly and unambiguously disclaimed any amount of pregelatinized starch outside the range of 10% to 50% by weight of the preparation. (Defs.' Br. 24.) Defendants quote Biogen Idec, Inc. v. GlaxoSmithKline LLC, 713 F.3d 1090, 1095 (Fed. Cir. 2013): "when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered."

The amendments and remarks filed on May 24, 2010 demonstrate an unequivocal surrender of claim scope: the applicants attempted to overcome rejections for obviousness over Fujihara in view of Salpekar with two actions. First, the applicants immediately amended the claims to surrender claim scope covering the use of pregelatinized starch in amounts under

10%.[19] Second, applicants, in the accompanying remarks, distinguished Salpekar as only teaching the use of pregelatinized starch in amounts under 10%. Through these two actions, the applicants clearly and unmistakably disclaimed inventive compositions containing pregelatinized starch in amounts under 10%: the applicants submitted amendments which surrendered this territory and also distinguished Salpekar on the basis of its teachings, focusing on what it taught about the effective amount of pregelatinized starch for superior dissolution profiles.[20]

The applicants continued to take this position. For example, in an undated amendment,[21] the applicants touted the advantages of the invention – high lurasidone amounts with rapid dissolution – and stated: "This combination of advantageous properties results from the presence of pregelatinized starch in the claimed oral preparation in an amount of 10 to 50% (wt/wt) . . ." (Reig-Plessis Dec. Ex. R at DEF-LURAS0008696.) This is clearly a statement about the invention generally – an oral composition with a high lurasidone content ratio, with rapid dissolution. The applicants attributed these key advantages of the invention to the presence of pregelatinized starch in the range of 10 to 50%, and distinguished the prior art on that basis.

In that same amendment, the applicants also argued that Salpekar taught away from the

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[19] This, by itself, constitutes an unequivocal surrender of claim scope to overcome an obviousness rejection.

[20] Note in particular the penultimate sentence in the applicants' arguments to overcome the obviousness rejection, as quoted above: "Therefore, those skilled in the art may understand that 4.45-8.85% of PGS is preferable for a tablet having a short disintegration time and a short dissolution time." (Reig-Plessis Dec. Ex. M at DEF-LURAS0008590.) The effect of this is that the applicants acknowledged that the combination of Fujihara with Salpekar could have motivated a skilled artisan to make a lurasidone formulation with a pregelatinized starch content under 10%.

[21] The Reig-Plessis declaration identifies this document as an amendment dated September 13, 2012. (Reig-Plessis Dec. ¶ 20.)

use of pregelatinized starch in the 10 to 50% range. (Id. at DEF-LURAS0008706.) They thus distinguished a prior art reference to overcome an obviousness rejection by arguing that it only taught the use of pregelatinized starch outside the range used in the invention.

Moreover, these are not isolated statements, only distantly connected to the '085 patent. In the "Background Art" section of the '085 specification, the patent states: "The pregelatinized starch is known to remarkably improve a disintegration and a dissolution of a pharmaceutical composition as described, for example, in Patent Document 3, but it is often used, typically, in 10% or less of contents as also described in Non-patent Document 1." '085 patent, col.2 ll.9-13. The specification identifies Non-patent Document 1 as the 1994 edition of the Handbook of Pharmaceutical Excipients. '085 patent, col.2 ll.17-18. This is highly significant. In the same undated amendment just discussed, the applicants used this reference to bolster their argument that Salpekar taught only the use of pregelatinized starch in amounts less than 10%:

> This supports the point that typically (conventionally) *less* than 10% (wt/wt) pregelatinized starch would have been used, which is consistent with the results Selpakar [sic] disclosed for the acetaminophen compositions.
>
> This conventional teaching would have led away from the present oral preparations.

(Reig-Plessis Dec. Ex. R at DEF-LURAS0008708.) This is an unmistakable acknowledgment that the use of 10% or less of pregelatinized starch to improve dissolution was well-known in the prior art. It is also an unmistakable surrender of such formulations to achieve patentability, as the applicants state clearly that such prior art uses taught away from the present oral preparations. Most crucially, the applicants put the statement of the prior art knowledge into the specification, which cannot change in continuation applications. This indicates that the applicants understood this to be a surrender of subject matter that would limit all future descending continuation

applications.

These statements unambiguously disavow formulations with less than 10% pregelatinized starch.

The key Federal Circuit case on prosecution disclaimer is Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003), in which the Court held:

> The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution. . .
>
> [W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.

This Court finds that, during prosecution of the parent patent, the applicants surrendered coverage of formulations containing less than 10% PGS. This meets the requirements for a finding of prosecution disclaimer under Federal Circuit law.

Prosecution disclaimer may be found where, as here, the applicants obtained the patent by distinguishing the prior art on certain grounds. The Supreme Court has held:

> It is, of course, well settled that an invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office. Claims as allowed must be read and interpreted with reference to rejected ones and to the state of the prior art; and claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent.

Graham v. John Deere Co., 383 U.S. 1, 33, 86 S. Ct. 684, 702 (1966) (citations omitted). The prosecution history shows that the applicants obtained the patent by distinguishing the prior art as teaching only formulations containing less than 10% pregelatinized starch, and narrowing the claims accordingly.

Plaintiffs, in opposition, try to make something out of the assertion that the applicants' remarks about Salpekar were not "the lead argument," without explaining the significance of this. (Pls.' Opp. Br. 22.) The law of prosecution disclaimer says nothing about whether statements of disavowal are made first or second. Plaintiffs also attempt to make something of the fact that the applicants used the phrase, "for the sake of argument." (Id.) This Court recognizes that this phrase appeared in the pertinent remarks and nonetheless finds that the applicants made a clear and unmistakable surrender of claim scope.

Plaintiffs also point to statements made by the examiner during the prosecution of later-occurring continuation applications, such as application number 17/733,204. For example, in the office action dated March 29, 2016, the examiner wrote: "although the instant claims do not explicitly recite 20-50% of pregelatinized starch, they encompass any concentration of pregelatinized starch and thus include this amount of this excipient recited in the claims of USP '085." (Flanagan Dec. Ex. S at LATUDA00000539.) Plaintiffs argue that this shows that the examiner understood the claims to allow any concentration of pregelatinized starch. While this may be true, it does not change this Court's determination that the applicants made an unmistakable disclaimer of scope during prosecution of the '085 patent. The Federal Circuit has stated:

> Although unilateral statements by an examiner do not give rise to a clear disavowal of claim scope by an applicant, it does not necessarily follow that such statements are not pertinent to construing claim terms. Statements about a claim term made by an examiner during prosecution of an application may be evidence of how one of skill in the art understood the term at the time the application was filed.

Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347 (Fed. Cir. 2005). The applicants' disclaimer during prosecution was unmistakable. The examiner's statements down the road

neither undermine nor change that determination.

Lastly, Plaintiffs attack Defendants' prosecution history case by observing that the applicants made not one, but two amendments limiting the pregelatinized starch content: there was the first amendment, and a subsequent amendment that changed the range, 10 to 50%, to 20 to 50%. The suggestion is that Defendants' use of one amendment, but not the other, demonstrates how arbitrary their argument is. Plaintiffs' argument mischaracterizes Defendants' position. Defendants based their prosecution disclaimer argument not only on the amendments, but also on the arguments made by the applicants in support of those amendments. (See, e.g., Defs.' Br. 22-24.) The applicants accompanied the first amendment with the remarks quoted above, in which this Court has found an unmistakable surrender of claim scope. The applicants accompanied the second amendment, however, with a disclaimer: "Applicant is not disclaiming any subject matter by the amendments provided herein, and reserves the right to file a continuation application with claims that include the canceled subject matter." (Reig-Plessis Dec. Ex. S at DEF-LURAS0008901.) This statement precludes a finding that the second amendment operated as an unmistakable surrender of claim scope.

Plaintiffs contend that the overall history of the '794 patent and its parent applications evidences not a binding disclaimer, but a process typical of patent prosecution with a chain of continuation applications. Plaintiffs cite Sanofi v. Watson Labs. Inc., 875 F.3d 636, 650 (Fed. Cir. 2017) (citations omitted), which states:

> Watson and Sandoz raise just one issue. They argue that the district court erred by failing to limit the claims of the '800 patent to exclude polysorbate surfactants. They point to the fact that, while prosecuting the parent application, which issued as U.S. Patent No. 7,323,493, Sanofi amended the sole independent claims (hence all claims) so as expressly to exclude pharmaceutical compositions with a "polysorbate surfactant" from the claims of the '493 patent. Based on that

> amendment, Watson and Sandoz contend that Sanofi made a "prosecution disclaimer" that also limits the scope of the claims of the '800 patent, despite the absence of any limiting language in the '800 patent's claims.We review the district court's rejection of this prosecution-disclaimer argument de novo. We agree with the district court.
>
> A prosecution disclaimer occurs when a patentee, either through argument or amendment, surrenders claim scope during the course of prosecution. But when the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply. In general, a prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor.
>
> In this case, all that Sanofi did, in prosecuting the application that issued as the '493 patent, was to write an express limitation into the claims: "provided that the pharmaceutical composition does not contain a polysorbate surfactant." That language does not appear in the '800 patent claims at issue. As the district court noted, Sanofi did not argue during prosecution that the unamended claim language of the '493 patent, or the disclosed invention generally, excluded polysorbate surfactants. In these circumstances, the process in this case fit a familiar pattern: an applicant adopts an explicit claim-narrowing limitation to achieve immediate issuance of a patent containing the narrowed claims and postpones to the prosecution of a continuation application further arguments about claims that lack the narrowing limitation. Without more than exists here, that process does not imply a disclaimer as to claims, when later issued in the continuation, that lack the first patent's express narrowing limitation.

The problem for Plaintiffs is one key sentence here: "Sanofi did not argue during prosecution that the unamended claim language of the '493 patent, or the disclosed invention generally, excluded polysorbate surfactants." (Id.) This distinguishes Sanofi from the instant case. In the instant case, this Court has found that the applicants, during prosecution of the '085 patent, argued that *the disclosed invention generally* excluded formulations with pregelatinized starch content under 10%. The applicants also distinguished two prior art references on the basis of pregelatinized starch content being under 10%. It is unmistakable that the applicants took the position that their claims should be allowed because the invention did not cover formulations with pregelatinized

starch content under 10%, which appeared in the prior art. This distinguishes Sanofi, which stands for the proposition that a narrowing amendment alone, without other disclaiming statements, does not operate as a prosecution disclaimer: the applicants in Sanofi made only a narrowing amendment, and no statements affirming the restricted view of the disclosed invention. Today's decision is entirely consistent with Sanofi, because the prosecution history of the '085 shows disclaiming statements in addition to a narrowing amendment.

In support of their contention that the applicants made no unmistakable disclaimer, Plaintiffs cite two more cases that do not help them. The first is 3M Innovative Props. Co. v. Tredegar Corp., 725 F.3d 1315, 1326 (Fed. Cir. 2013), which stands for this proposition: "Where an applicant's statements are amenable to multiple reasonable interpretations, they cannot be deemed clear and unmistakable." Had Plaintiffs proposed an alternative reasonable interpretation of the applicants' statements distinguishing Salpekar, this case might be apposite, but they did not do so. In the second, Resqnet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1383 (Fed. Cir. 2003), the Federal Circuit found that the parent patent's "prosecution history is irrelevant to the meaning of this limitation because the two patents do not share the same claim language." In the instant case, the two patents use the same claim term, "a pregelatinized starch."

The legal basis for today's finding of prosecution disclaimer is well-illustrated in Tech. Props. Ltd. LLC v. Huawei Techs. Co., 849 F.3d 1349, 1358 (Fed. Cir. 2017). There, the applicant overcame a rejection for obviousness over Magar, a prior art reference. To traverse the Magar rejection, the applicant made arguments distinguishing the claimed invention from the disclosures of Magar. The Court affirmed the district court's determination that these statements operated as prosecution disclaimers: "The patentee's disclaimer may not have been necessary, but

its statements made to overcome Magar were clear and unmistakable." Id. In the instant case, the statements made to overcome Salpekar are similarly clear and unmistakable; they constitute prosecution disclaimers.

This Court concludes that, during the prosecution of the '085 patent, the applicants unmistakably surrendered coverage of formulations with a pregelatinized starch content under 10% (wt/wt).

Defendants next argue that the disclaimer found in the prosecution of the '085 patent binds and restricts the interpretation of the same claim term in patents which matured from the descendant continuation applications. "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999).[22] In the instant case, multiple patents derived from the same initial application. Under Elkay, the disclaimer found in the prosecution history of the '085 patent applies to subsequently issued patents that contain the same claim limitation. The '085 patent and the '794 patent contain the same claim limitation, "a pregelatinized starch." The interpretation of the meaning of this term in the '794 patent is thus restricted by the unmistakable surrender of subject matter during prosecution of the '085 patent.

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[22] See also Alloc, Inc. v. ITC, 342 F.3d 1361, 1372 (Fed. Cir. 2003) ("the independent claims of the '907, '410, and '267 patents incorporate the same limitations adopted by the applicant to secure allowance of the parent '621 patent"); Augustine Med., Inc. v. Gaymar Indus., 181 F.3d 1291, 1300 (Fed. Cir. 1999) ("the prosecution history of a parent application may limit the scope of a later application using the same claim term"); Microsoft Corp. v. Multi-Tech Sys., 357 F.3d 1340, 1349 (Fed. Cir. 2004) ("the prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application"); Omega, 334 F.3d at 1333 ("As long as the same claim limitation is at issue, prosecution disclaimer made on the same limitation in an ancestor application will attach").

"Although a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited." Hakim v. Cannon Avent Grp., PLC, 479 F.3d 1313, 1318 (Fed. Cir. 2007). While the parties dispute whether a disclaimer occurred during prosecution of the '085 patent, they agree that no rescission followed. Plaintiffs' only argument against Defendants' interpretation is that no disclaimer occurred; this Court has concluded the contrary. Plaintiffs have not pointed to any reason why the unmistakable disclaimer found in the prosecution history of the parent patent should not restrict the interpretation of the same claim term in the descendant patent.[23] This Court concludes that the surrender of subject matter found during prosecution of the '085 patent applies to the '794 patent.

Nonetheless, this Court does not fully accept Defendants' proposed construction, "pregelatinized starch in the range of 10% to 50% by weight of the preparation." During prosecution of the '085 patent, at issue was the overlap between the proposed invention and Salpekar, but at only the bottom of this range (0 to 10, 15, or 20%), not at the top (> 50%). Neither party has pointed to any evidence that the applicants surrendered formulations containing greater than 50% pregelatinized starch. This Court thus finds no basis to limit the upper end of the range of pregelatinized starch. The Court therefore adopts neither party's proposed

[23] Indeed, the omission of any such argument is striking. At oral argument, Plaintiffs did not argue that a disclaimer during the prosecution of the '085 patent should not restrict the interpretation of the '794 patent. Rather, the closest Plaintiffs came to such an argument was to comment, at several points, that the claims in the '085 patent and those at issue in the '794 patent are very different. Plaintiffs have not proposed a legal theory that makes use of the differences between the claims in the two patents.

construction of "a pregelatinized starch," and finds it sufficient to hold that the applicants surrendered coverage of all formulations containing less than 10% pregelatinized starch (wt/wt). Therefore, "a pregelatinized starch" means "a pregelatinized starch with a content greater than or equal to 10% (wt/wt)."

In conclusion, this Court resolves the present disputes over claim construction as follows: 1) In the '827 patent; "a patient" and "the patient" have their ordinary meaning, which is "one or more patients;" 2) the construction of "clinically significant weight gain" is postponed until expert evidence is presented, whether at summary judgment or at trial; and 3) as to the '794 patent, "a pregelatinized starch" means "a pregelatinized starch with a content greater than or equal to 10% (wt/wt)."

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: October 5, 2018